



## UNITED STATE DEPARTMENT OF COMMERCE Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | AT           | ATTORNEY DOCKET NO. |  |
|-----------------|-------------|----------------------|--------------|---------------------|--|
|                 |             |                      |              |                     |  |
|                 |             | ¬ [                  | EXAMINER     |                     |  |
|                 |             | [                    | ART UNIT     | PAPER NUMBER        |  |
|                 |             |                      |              | 6                   |  |
|                 |             |                      | DATE MAILED: |                     |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

| •         |        |         |
|-----------|--------|---------|
| ~ · · · · | A      | ^       |
| INTICO    | ACTION | Summany |
| UIIICE    | 70000  | Summary |
|           |        |         |

Application No. **09/508,635** 

Applican

Examiner

Group Art Unit

David Lukton 1653

Ballevre

X Responsive to communication(s) filed on May 25, 2000 This action is FINAL. prosecution as to the merits is closed Since this application is in condition for allowance except for formal matters, in accordance with the practice under Ex parte Quay 1935 C.D. 11; 453 O.G. 213. A shortened statutory period for response to this action is set to expire 30 0 0 0 0 or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a) Disposition of Claim \_\_\_\_\_\_ is/are pending in the applicat X Claim(s) 1-10 Of the above, claim(s) \_\_\_\_\_\_\_is/are withdrawn from consideration Claim(s) \_\_\_\_\_\_ is/are rejected. is/are objected to. Claim(s) X Claims 1-10 are subject to restriction or election requirement. **Application Papers** See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The drawing(s) filed on \_\_\_\_\_\_ is/are objected to by the Examiner. The proposed drawing correction, filed on \_\_\_\_\_\_ is \_\_approved \_\_disapproved. The specification is objected to by the Examiner. The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). Some\* None of the CERTIFIED copies of the priority documents have been received. received in Application No. (Series Code/Serial Number) received in this national stage application from the International Bureau (PCT Rule 17.2(a)). \*Certified copies not received: \_\_ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). Attachment(s) Notice of References Cited, PTO-892 Information Disclosure Statement(s), PTO-1449, Paper No(s). Interview Summary, PTO-413 Notice of Draftsperson's Patent Drawing Review, PTO-948 Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Serial No. 508,635 Art Unit 1653

A restriction is imposed, as set forth below. First, however, the following two subgenera are defined:

G1: this subgenus is limited to a method of using a dietary protein to increase protein concentration and synthesis in the intestine, the duodenum, or the jejunum

**G2**: this subgenus is limited to a method of using a dietary protein to maintain muscle protein synthesis, or for the treatment of muscular atrophy.

Restriction to one of the following inventions is required under 35 U.S.C. §121:

I. Claims 1-6, 8-10, drawn to a method of using dietary protein to increase protein synthesis in a selected organ, wherein the method includes G1, but excludes G2, classified in, e.g., 514/002.

II. Claims 1 and 7, drawn to a method of using dietary protein to increase protein synthesis in a selected organ, wherein the method includes G2, but excludes G1, classified in, e.g., 514/002.

The claimed inventions are distinct. One is directed at improving gut function, the other to treatment of muscular atrophy. Moreover, as observed by the examiner of the PCT application, the claimed invention does not "define a contribution" over the prior art; as such, unity of invention is lacking.

Serial No. 508,635 Art Unit 1653

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect a specie for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. A specie is a fully defined "dietary protein". It should include information such as (a) the degree of hydrolysis, if the protein is hydrolyzed. (b) the lower limit on the weight percent of di and tri-peptides, if any, (c) if the protein is hydrolyzed, the source of the protein (e.g., casein or whey protein) should also be specified, (d) the presence or absence of a carbohydrate and fat in the formulation should also be specified. In addition, in the event that Group I is selected, a specific "organ" or body part should be selected (e.g., intestine, duodenum, or jejunum).

Serial No. 508,635 Art Unit 1653

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are witten in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

PATENT EXAMINER
GROUP 1800